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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,581	04/12/2004	Robert Burgmeier	S63.2-10865-US01	2645
490	7590 06/17/2005		EXAMINER	
•	RETT & STEINKRA	· TRAN, THAO T		
6109 BLUE ( SUITE 2000	6109 BLUE CIRCLE DRIVE			PAPER NUMBER
	KA, MN 55343-9185		1711	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/822,581	BURGMEIER ET AL.			
Office Action Summary	Examiner	Art Unit			
	Thao T. Tran	1711			
The MAILING DATE of this communication a Period for Reply	appears on the cover sheet w	rith the correspondence address			
A SHORTENED STATUTORY PERIOD FOR REI THE MAILING DATE OF THIS COMMUNICATIO  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a  - If NO period for reply is specified above, the maximum statutory peri  - Failure to reply within the set or extended period for reply will, by sta Any reply received by the Office later than three months after the may earned patent term adjustment. See 37 CFR 1.704(b).	N. 1.136(a). In no event, however, may a reply within the statutory minimum of thi iod will apply and will expire SIX (6) MO attue, cause the application to become A	reply be timely filed  rty (30) days will be considered timely.  NTHS from the mailing date of this communication.  BANDONED (35 U.S.C. § 133).			
Status		•			
1) Responsive to communication(s) filed on _					
·	2a) ☐ This action is <b>FINAL</b> . 2b) ☐ This action is non-final.				
3)☐ Since this application is in condition for allow					
closed in accordance with the practice unde	er Ex parte Quayle, 1935 C.I	D. 11, 453 O.G. 213.			
Disposition of Claims					
4) Claim(s) 1-30 is/are pending in the application	on.				
4a) Of the above claim(s) 14-29 is/are withd	rawn from consideration.				
5) Claim(s) is/are allowed.		•			
6)⊠ Claim(s) <u>1-13 and 30</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and	d/or election requirement.				
Application Papers		,			
9) The specification is objected to by the Exam	iner.				
10) The drawing(s) filed on is/are: a) a	accepted or b) objected to	by the Examiner.			
Applicant may not request that any objection to t		· · · · · · · · · · · · · · · · · · ·			
Replacement drawing sheet(s) including the corr	ection is required if the drawing	g(s) is objected to. See 37 CFR 1.121(d).			
11) The oath or declaration is objected to by the	Examiner. Note the attache	d Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119	•				
12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of:  1. ☐ Certified copies of the priority documents.		§ 119(a)-(d) or (f).			
2. Certified copies of the priority docume		Application No.			
3. Copies of the certified copies of the p					
application from the International Bure					
* See the attached detailed Office action for a I	, , , , , , , , , , , , , , , , , , , ,	received.			
Americans					
Attachment(s)  1) Notice of References Cited (PTO-892)	4) Intension	Summary (PTO-413)			
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(	s)/Mail Date			

U.S. Patent and Trademark Office PTOL-326 (Rev. 1-04)

Paper No(s)/Mail Date 8/2/04.

3) 🖾 Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)

6) Other: \_\_\_\_.

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#### **DETAILED ACTION**

#### Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-13 and 30, drawn to an article, classified in class 428, subclass 423.1.
  - II. Claims 14-29, drawn to a method of making an article, classified in class 264, subclass 3.3.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by a different process, such as a coating process to form the laminate article.
- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
- 4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

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5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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- 6. During a telephone conversation with Mr. Walter Steinkraus on April 22, 2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-13 and 30. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-29 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
- Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### Claim Rejections - 35 USC § 112

- 8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 9. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is indefinite because it is unclear to the examiner if Applicants are trying to indicate that the inner and outer layers are the first and second layers respectively. If so, please state so.

Claim 1 recites the limitation "the inner and outer layers" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Note: the examiner is interpreting that the inner and outer layers are the first and second layers that are formed from the first and second polymer materials respectively.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the 10. basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 11. Claim 30 is rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (US Pat. 5,195,969) or Samuelson et al. (US Pat. 6,464,683).

Wang teaches a laminate in a medical balloon or a catheter, the laminate comprising an innermost layer of polyethylene, an outermost layer of Nylon (polyamide), and a layer of Plexar sandwiched in between. Plexar is an anhydride-modified polyolefin. (See Figs 3-4; col. 4, ln. 14-15, 46-49).

Samuelson teaches a laminate in a medical tubing, the laminate comprising an outer layer 16, a core layer 12, and an intermediate tie layer 14 interposed between the outer layer and the core layer (see abstract; Fig. 1). The outer layer comprises a polyester or polyamide; the core

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layer comprises a polyethylene; and the intermediate tie layer comprises a polymeric material comprising functionality capable of adhering outer layer 16 to core layer 12. (See col. 6, ln. 5-6, 41-45, 57-59). The polymer of the intermediate tie layer comprises modified olefinic polymer having an anhydric moiety or maleic acid (see col. 7, ln. 12-51).

## Claim Rejections - 35 USC § 103

- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang or Samuelson in view of Shimura et al. (US Pat. 5,441,488).

Wang teaches a laminate in a medical balloon or a catheter, the laminate comprising an innermost layer of polyethylene, an outermost layer of Nylon (polyamide), and a layer of Plexar sandwiched in between. Plexar is an anhydride-modified polyolefin. (See Figs 3-4; col. 4, ln. 14-15, 46-49).

Samuelson teaches a laminate in a medical tubing, the laminate comprising an outer layer 16, a core layer 12, and an intermediate tie layer 14 interposed between the outer layer and the core layer (see abstract; Fig. 1). The outer layer comprises a polyester or polyamide; the core layer comprises a polyethylene; and the intermediate tie layer comprises a polymeric material comprising functionality capable of adhering outer layer 16 to core layer 12. (See col. 6, ln. 5-6,

41-45, 57-59). The polymer of the intermediate tie layer comprises modified olefinic polymer having an anhydric moiety or maleic acid (see col. 7, ln. 12-51).

However, neither Wand nor Samuelson teaches the amount of the modifying compound of the polyolefin in the intermediate layer.

Shimura teaches a modified polyolefin as an adhesive in a laminate, the modified polyolefin comprising maleic anhydride is deposited on polyolefin or polyamide (see col. 4, ln. 51-56; col. 5, ln. 1-7). The content of acid anhydride is 0.5-50% (see col. 5, ln. 9-10). The composition further comprises a catalyst, such as tertiary amine, to promote the reaction of the acid anhydride (see col. 5, ln. 40-43).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have employed the modified polyolefin with the acid anhydride content and the catalyst, as taught by Shimura, in the tie layer of Wang or Samuelson, for the purpose of enhancing adhesion between the tie layer and the outer and inner layer. This is because Shimura teaches that the use of such modified polyolefin and catalyst would have improved bonding and crosslinking between the modified polyolefin and polyamide or polyester.

### **Contact Information**

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thao T. Tran whose telephone number is 571-272-1080. The examiner can normally be reached on Monday-Friday, from 9:00 a.m. - 5:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 14, 2005

Thew Tran

THAO T. TRAN
PATENT EXAMINER